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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,935	06/08/2001	Daniel Pinto	13294-002001	1394

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EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 01/28/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/877,935

Applicant(s)

PINTO ET AL.

Examiner

Celine X Qian

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 13-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☒ Other: *sequence letter*.

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DETAILED ACTION

Claims 1-31 are pending.

Election/Restrictions

Applicant's election without traverse of Group I in Paper No. 14 is acknowledged.

Accordingly, claims 13-31 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-12 are currently under examination.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a nucleotide sequence, which is a product of nature, therefore not patentable. Reciting "an isolated nucleotide acid molecule..." may obviate this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 9-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: “*specification* shall contain a written description of the invention. . . [emphasis added].” The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that “as of the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Claim 1 recites a 9kb nucleotide region or a fragment of a said region 5’ to mouse villin gene which encompasses a broad genus of nucleic acid molecules of different sizes that promote the transcription of the murine gene. Claim 12 recites a 9kb fragment from –3.5 to +5.5 or a

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fragment of said region that has the promoter function. The specification discloses a 9kb fragment from -3.5 to +5.5 and five fragments of this region that have promoter activity in transient transfection assays. However, the specification fails to teach what elements these fragments must comprise for them to be functional promoter other than HS II, III and IV. The specification also fails to teach whether other 9kb fragments, for example, outside the region that is disclosed by the specification, can also promote villin gene transcription. As such, the structural and function relationship between the 9kb nucleotide fragment and its promoter function is missing. Therefore, the specification fails to describe a representative number of species by their complete structure or other characterizing features. The written description requirement is not met.

Claims 9 and 10 recite a 9kb fragment comprising -3.5 to translation start site of the villin gene wherein the intron 1 or part of intron 1 is deleted. The specification teaches deletion of the entire intron one retains the promoter activity of this fragment. The specification also teaches that deletion of the HS II within this region abolishes promoter function. However, the specification fails to teach whether there are other elements, for example HS I within this region also critical for promoter function. The specification fails to describe any nucleotide fragments with partial deletion of intron 1 that retains promoter function. As such, the structural and function relationship between the 9kb nucleotide fragment with partial intron deletion and its promoter function is missing. Therefore, the written description requirement is not met.

Claim 11 recites a 9kb nucleotide fragment comprises nucleotide regions having a regulatory activity affecting the level of expression of the murine villin gene. As discussed the above, the specification only teaches one 9kb region extending from -3.5 to +5.5 that having

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regulatory activity affecting the level of expression of the murine villin gene. Since the specification fails to describe the necessary elements that are required for the promoter function, the specification fails to describe a representative number of species by their complete structure or other characterizing features. Therefore, the written description requirement is not met. For reasons discussed above, the specification has failed to describe the invention in such a way to convey one skilled in the art that the inventors had possession of the invention at the time of filing.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-12, the word “derived” renders the claims indefinite because the nature and the number of derivative process are unknown. As such, the metes and bounds of the claims cannot be established.

The recitation of “having a size of 9kb on an agarose gel” also renders the claims indefinite because the size of the nucleotide sequence is unclear. Is it 9kb only on an agarose gel or is it a different size measured by other methods?

Regarding claim 6 and 8, the term “at around” or “from around” renders the claims indefinite because it is unclear what position Applicants are referring to. For example, is -200, -130 or -60 encompassed by the claim?

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Regarding claim 7, the recitation of "nucleotide fragment extending...to the transcription site and further comprises the translation start site" renders the claim indefinite because it is unclear what exact elements this nucleotide fragment comprises. In other words, it is unclear whether this fragment comprises the region in between transcription start site and translation start site.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
January 27, 2003

Anne-Marie Falk
ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER